CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

INITIAL STATEMENT OF REASONS FOR THE PROPOSED ADOPTION OF INTELLECTUAL PROPERTY REGULATIONS FOR NON-PROFIT ORGANIZATIONS

HEARING DATE: June 19, 2006; 9:00 a.m; Office of the CIRM – 210 King Street, San Francisco, CA 94117.

SUBJECT MATTER OF PROPOSED REGULATIONS: Intellectual Property Policy for Non-Profit Organizations

SECTIONS AFFECTED: The proposed regulations adopt Chapter 3 and sections 100300, 100301, 100302, 100303, 100304, 100305, 100306, 100307, 100308, 100309 and 100310 of Title 17 of the California Code of Regulations.

SPECIFIC PURPOSE AND FACTUAL BASIS FOR EACH ADOPTION:

SECTION 100300 – SCOPE:

Purpose:

Section 100300 establishes the scope of the regulations comprising Chapter 3. The regulations in this chapter apply to all CIRM grant awards issued on or after the effective date of the regulations. Amended regulations become applicable to ongoing grants on the start date of the next non-competitive renewal period. Principal investigators, program directors and other officials with active grants will receive notification of revised grant terms as they are adopted by the CIRM.

Rationale: This section is necessary to define the circumstances and extent to which this chapter is to be applied. Because grants can exist over multiple numbers of years, it is necessary to indicate how revised grant terms are to be incorporated into existing grants.

SECTION 100301 – INTELLECTUAL PROPERTY REGULATIONS – DEFINITIONS:

Purpose:

The following definitions shall apply to language contained in Sections 100300 through 100310 of these regulations.

(a) "Authorized Organizational Official." The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the laws, regulations, requirements, and conditions that apply to grant applications or grant awards.

(b) "Award." The provision of funds by CIRM, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

(c) "Bayh-Dole Act." Section 6(a) of the federal Patent and Trademark Law Amendments Act (96 P.L.517,1980) as amended (35 U.S.C. §§200 212).

(d) "Biomedical Materials." Entities of biomedical relevance produced as a consequence of scientific research including but not limited to unique research resources such as synthetic compounds, organisms, cell lines, viruses, cell products, cloned DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized and/or genetically defined cells, including normal and diseased human cells, monoclonal antibodies, hybridoma cell lines, microbial cells and products, viruses and viral products, recombinant nucleic acid molecules, DNA probes, nucleic acid and protein sequences, certain types of animals including transgenic mice and other intellectual property such as computer programs.

(e) "Data." The recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples).

(f) "For-Profit Organization." An organization, institution, corporation, or other legal entity that is organized or operated for the profit or financial benefit of its shareholders or other owners.

(g) "Grantee/Grantee Organization." The individual or organization awarded a grant by CIRM that is legally responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activity. The grantee is the entire legal entity even if a particular component is designated in the NGA. All University of California grantee institutions shall be considered as separate and individual grantee institutions.

(h) "Grantee Organization's Share." The revenues received by a grantee organization under a commercial license of a CIRM-funded patented invention remaining after deducting the inventor's share of those revenues.

(i) "Invention." A discovery that is or may be patentable (novel, useful and non-obvious) or otherwise protectable under Title 35 of the United States Code.

(j) "Invention Disclosure." A description of an invention that triggers a patent bar under U.S. Patent Law.

(k) "Invention Disclosure Form." A written notification to CIRM that a CIRM-funded patentable invention has been made.

(l) "Invention Utilization Report." Applicable to grantee organizations that have previously filed an Invention Disclosure Form, this annual report is a written description of efforts made by authorized organizational officials to commercialize CIRM-funded patentable inventions. This report will include information about the status of development, date of first commercial sale or use and any licensing fees and/or gross royalties received by the grantee organization relating to CIRM-funded patented inventions.

(m) "Inventor." A person who thinks of, finds, discovers, or creates an invention during the project period of a CIRM grant and using CIRM funds as determined under U.S. Patent Law.

(n) "License Agreement." An agreement by which a patent owner allows another party to make, use and/or sell an invention protected by a patent.

(o) "Licensing Activities." Actions taken by authorized organizational officials, the desired outcome of which is a contractual agreement under which the grantee organization grants permission to another party to use intellectual property under specific conditions.

(p) "Licensing Fee." A one-time cost payable by a licensee to the patent owner typically associated with execution of a license agreement.

(q) "Materials Transfer Agreement." A document which governs the exchange of a substance, element or item (material) to another party for the purposes of research. It limits the commercial exploitation of the material without the permission of the provider party.

(r) "No-Cost License." An agreement to practice an invention protected by a patent where no licensing fee, royalty or any other payment is required of the licensee.

(s) "Non-Profit Organization." A university or other institution of higher education or an organization of the type described in 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501 (c) and exempt from taxation under 501 (a) of the Internal Revenue Code (25 U.S.C. 501 (a)) or any non-profit scientific or educational organization qualified under a state non-profit organization statute.

(t). "Notice of Grant Award." The document that notifies the grantee and others that an award has been made, contains or references all terms and conditions of the award, and documents the obligation of CIRM funds.

(u) "Office of Technology Transfer." The office at a grantee institution that is responsible for evaluating, protecting, monitoring and managing an invention portfolio for the public good through overseeing invention disclosures, patent filings, patent prosecution, and negotiating and monitoring licensing agreements.

(v) "Patentable Invention." A novel, useful and non-obvious invention that advances science and enables new useful applications including therapeutics or diagnostic tools, as determined under relevant patent law.

(w) "Principal Investigator/Program Director." The principal investigator ("PI") or program director ("PD") is an individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and CIRM for the proper conduct of the project or activity. For training programs or similarly structured programs, the PD is the same as the PI.

(x) "Project period." The total amount of time for which CIRM promises to fund a grant and authorizes a grantee to conduct the approved work of the project described in the application.

(y) "Research Exemption." The ability to use patented inventions for research purposes free from the threat of patent infringement or costs of licensing fees, royalties or any other payments.

(z) "Research Tool." A composition or method that broadly facilitates subsequent research.

Rationale:

To make specific the language and terminology used in formulating these regulations.

SECTION 100302 – INVENTION REPORTING REQUIREMENTS.

Purpose:

To ensure efficient use of CIRM-funded inventions, grantees are required to notify the CIRM of certain progress invention-related activities.

Subdivision (a) states the general rule that grantee organizations are required to have written agreements with researchers that require prompt disclosure of inventions made in the performance of CIRM-funded research.

Subdivision (b) This subdivision describes the procedure and timeline for disclosure by a grantee organization of an invention. The disclosure must provide sufficient information to inform the CIRM of the nature and purpose of the invention. If the invention is the subject of a manuscript, the grantee must identify the manuscript and the date of its submission.

Subdivision (c) requires grantees to notify the CIRM on an annual basis the filing of patent applications for inventions made in performance of CIRM-funded research.

Subdivision (d) requires grantees to notify the CIRM annually regarding licensing agreements of inventions made in performance of CIRM-funded research.

Subdivision (e) requires grantees to submit an Invention Utilization Report identifying all CIRM-funded inventions, patents and a description of efforts made to utilize CIRM-funded inventions. The subdivision details specific information that must be disclosed regarding licenses of the CIRM-funded inventions.

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) To fulfill this role, the CIRM must monitor the work of grantees and ensure that inventions are pursued and exploited wherever possible. Therefore, this regulation is necessary to ensure that the CIRM is kept apprised whenever inventions are made and the steps taken or not taken regarding patents of those inventions. In addition, the reporting of licensing agreements ensures that the CIRM is able to determine whether CIRM-funded inventions are being used appropriately in the search for therapies and cures.

SECTION 100303. PUBLICATION REQUIREMENTS.

Purpose:

This section identifies the procedures and content for publication of CIRM-supported research results. This section requires submission of copies of the publication to the CIRM, identification of where the MTA or similar document may be found, and a sample acknowledgment of CIRM funding.

Rationale:

CIRM policy mandates that results and accomplishments of the activities it funds be made available to the public. Moreover, the CIRM is charged with ensuring that all grants and loan awards be subject to intellectual property agreements that balance the opportunity of the State to benefit from the patents, royalties and licenses that result from the research funded by the CIRM. (§ 125290.30, subd. (h).) The CIRM also supports broad sharing of intellectual property of all kinds and encourages the timely publication of scientific articles in open-access journals that provide immediate access to scientific accomplishments by the scientific community and general public. It is the CIRM's intention to create a database for tracking CIRM-funded inventions, patent applications and license agreements that involve CIRM-funded patented inventions based on information received from grantee organizations. Non-confidential information about CIRM-funded intellectual property may be shared with the public through a CIRM annual report. As a result, this regulation is necessary to ensure CIRM is aware of

CIRM-supported research results that the grantee deems worthy of publishing. The advance press release requirement also ensures the CIRM is kept abreast of and can report important progress of CIRM-supported research.

Subdivisions (a) through (c) ensure the CIRM can support sharing of research findings with the scientific community and the general public as a whole through the creation of a repository for such findings. This resource is intended to allow access by the scientific community and the general public to summaries of published scientific articles resulting from CIRM-funded projects. The regulation supports this disclosure by requiring abstracts to be written by the authors of scientific articles specifically for the general public and submitted to the CIRM within 60 days of the publication of the corresponding scientific articles.

SECTION 100304. BIOMEDICAL MATERIALS.

Purpose:

This section requires grantees to share biomedical materials described in published scientific articles for research purposes within a certain time after a receipt of a request unless legally prohibited from doing so. The section provides for CIRM-approved deviation in some circumstances and provides that authors may provide requestors with information on how to reconstruct or obtain the material. The section requires materials to be shared without cost or at cost.

Rationale:

It is expected that intellectual property of all types will be created as a consequence of CIRM grants and contracts. This regulation is intended to provide recipients of CIRM funding with guidance concerning appropriate terms for disseminating and acquiring unique research resources developed with CIRM funds and is designed to assist recipients in complying with their obligations under the Bayh-Dole Act and CIRM funding policy. In order to achieve maximum public benefit, data and biomedical materials (including research tools) should be as freely available as possible in the public domain.

SECTION 100305. PATENT APPLICATIONS:

Purpose:

This section states that grantees are responsible for bearing costs associated with patents and patent applications for CIRM-funded inventions. This section requires grantees to report annually patent applications pertaining to CIRM-funded inventions.

Rational:

It is not a policy of the CIRM to fund costs associate with patent applications. This regulation is necessary to ensure grantees are aware of conditions of their award. Consistent with the CIRM's oversight role of CIRM-funded research, the report requirement of subdivision (b) is necessary to ensure the CIRM is aware of all patent activity made in the performance of CIRM-funded research.

SECTION 100306. LICENSING CIRM-FUNDED PATENTED INVENTIONS:

Purpose:

This section describes the responsibilities of grantees for licensing activities of CIRM-funded patented inventions.

Subdivision (a) states it is the responsibility of grantees to pursue all licensing activities related to CIRM-funded patented inventions and must report that activity to the CIRM on an annual basis.

Subdivision (b) requires grantees to negotiate non-exclusive licenses of CIRM-funded inventions whenever possible and describes those circumstances under which exclusive licenses are permissible. In such circumstances, grantees must document the development and commercialization capabilities of the intended licensee and include terms addressing the therapeutic and diagnostic uses for which the invention is applicable.

Subdivision (c) requires grantees to include terms in exclusive licenses describing commercial development plans and relevant milestones for assessment of progress.

Subdivision (d) allows exclusive licenses for inventions relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. Licensees will be required to provide to patients whose therapies and diagnostics will be purchases in California with public funds at a cost not to exceed the federal Medicaid price.

Subdivision (e) requires grantees to monitor the performance of exclusive licensees ton ensure timely development of the invention. This section provides for modification or termination of a license in the event that a licensee is unable to fully develop the rights granted.

Subdivision (f) requires grantees to negotiate grounds for modification or termination of the license and provides examples.

Subdivision (g) requires monitoring of development activities of licensees by grantees to determine compliance with the terms of the license agreement and must report those activities annually to the CIRM. **Subdivision (h)** requires grantees to modify or terminate license rights where necessary and to report such action to the scientific program officer at the CIRM.

Rationale:

Due to the importance of effective patent licensing to the development and availability of new products arising from CIRM-funded inventions, the CIRM licensing policy includes several important elements such as appropriate use of non-exclusive and exclusive licenses, diligent efforts to commercialize CIRM-funded inventions and plans for access to resultant therapies and diagnostics for qualified patients in California.

For inventions with potential preventive, diagnostic, or therapeutic uses, where some type of exclusivity (and therefore patent protection) is necessary for product development, licensing of the patent rights is the primary vehicle for transferring the technology to commercial partners.

Grantee organizations are responsible for licensing activities including identification of potential licensees, negotiation of license agreements and documentation of development progress. Grantee organizations are required elsewhere to submit a licensing activities report for CIRM-funded patentable inventions on an annual basis.

CIRM seeks to ensure development of each invention for the broadest possible applications, optimizing the number of products developed from CIRM-funded inventions. This is accomplished first and foremost through diligent assertion of inventorship rights to inventions in accordance with current patent law. In addition, CIRM policy is for grantees to retain those ownership rights for transfer to the private sector through licensing instead of assignment. In the due diligence phase of licensing activities, grantee organizations are required to document the development and commercialization capabilities of the intended licensee, and include terms in the license agreement that address all relevant therapeutic and diagnostic indications for which the invention is applicable. This strategy allows CIRM grantee organizations to engage in licensing negotiations which ensure the broadest and most expeditious development of new products.

CIRM encourages the use of non-exclusive licenses and recognizes that exclusive licenses may be required to enable development of therapies and diagnostics. Grantee organizations shall grant exclusive licenses involving CIRM-funded patented inventions relevant to therapies and diagnostics only to organizations with plans to provide access to resultant therapies and diagnostics for uninsured California patients. In addition, such licensees will agree to provide to patients whose therapies and diagnostics will be purchased in California by public funds the therapies and diagnostics at a cost not to exceed the federal Medicaid price. These access plans may be made available by CIRM for review by the ICOC and the general public on an annual basis.

CIRM seeks to ensure that licensees of CIRM-funded patented inventions obtain the appropriate scope of rights necessary for them to develop potential applications of the invention while optimizing public good through the widespread use of the invention.

SECTION 100307. RESEARCH EXEMPTION

Purpose:

This section requires grantees to allow California research institutions to use the grantee's CIRM-funded patented inventions for no cost for research purposes. To ensure access, grantees are required to provide for such use in licenses of such inventions.

Rationale:

Research is a critical element of technological and medical progress. However, research activities may have unintended intellectual property implications. Under the Patent Act of 1952, any individual who makes, uses, sells, offers to sell or imports into the United States a patented invention without the authorization of the patent owner faces liability for infringement. The Patent Act of 1952 does not authorize a generally applicable research exemption. To the extent that researchers use another's patented invention without authorization, they may face liability for patent infringement. A research exemption (also known as "research use exemption" or "experimental use exemption") is the ability to experiment with patented inventions free from the threat of patent infringement or costs of licensing fees or royalties.

To promote the advancement of research and medical therapies through broad use of patented inventions developed under CIRM funding, grantee organizations agree that California research institutions may use their CIRM-funded patented inventions for research purposes at no cost. Grantee organizations shall ensure that such use is preserved in their licenses of CIRM-funded patented inventions. This policy will allow researchers to experiment with state-of-the-art technology generated as a consequence of CIRM funding without constraints which might otherwise apply under patent law.

SECTION 100308. REVENUE SHARING

Purpose:

This section describes the requirements of grantees with respect to the sharing of revenues obtained by licensing and developing CIRM-funded inventions.

Subdivision (a) requires grantees to share net revenues with inventors in accordance with the grantee's existing policy. The subdivision defines net revenues as gross revenues minus the inventor's share and direct costs incurred in the generation and protection of the patents from which the revenues are received.

Subdivision (b) describes the formula for computing payment to the State of California of the state's share of the grantee's revenues from licensing agreements. This provision requires payment to the state of 25% of the grantee's share after payments to inventors when revenues reach $500,000 or more, as adjusted for inflation.

Subdivision (c): Where multiple sources of funding were used for the creation of the patented invention, the return to the State of California of any revenues shall be proportionate to the support provided by the CIRM relative to the other funding.

Subdivision (d) reiterates the Proposition 71 requirement that the state's share of revenues earned under these provisions shall be used to support scientific research or education.

Rationale:

CIRM seeks to obtain a financial return on the public's research investment through the recovery of 25% of revenues from the grantee organization's (not the inventor's) share of revenues from licenses for CIRM-funded patented inventions. Consistent with their Bayh-Dole obligations, grantee organizations must share a fraction of revenues with the inventor(s). The CIRM-mandated 25% fee will go to the General Fund of the State of California unless such action violates any federal law. CIRM expects the balance of remaining revenues earned by the grantee organization to be applied for the support of research or education.

CIRM recognizes that administrative costs associated with filing patent applications, maintaining patent portfolios and carrying out licensing activities are a major financial burden for grantee organizations whether or not an invention is successfully licensed and results in any licensing revenues. To defray administrative costs associated with patent expenses, CIRM will recover funds from a grantee organization when net revenues from a license or licenses of a CIRM-funded patented invention exceed $500,000 in the aggregate. Net revenues are defined as gross revenues minus the inventor's share and direct costs incurred in the generation and protection of the patents from which the revenues are received.

CIRM also recognizes that funds from multiple sources may be used in the creation of intellectual property in the course of scientific research. In the event that CIRM partially funds research that leads to a licensed patented invention with revenues in excess of $500,000, the return to the State of California will be proportionate to the CIRM financial support for the research that resulted in the invention.

SECTION 100309. PRESS RELEASE REQUIREMENTS

Purpose:

This section requires grantees to notify the CIRM prior to any press release that refers to certain activities regarding CIRM-funded research. The regulation requires the grantee to coordinate with the CIRM any joint press releases when the CIRM expresses interest in doing so.

Rationale:

This regulation is necessary to the CIRM is apprised of current significant developments regarding CIRM-funded research and ensure proper attribution to the CIRM and the State of California for the CIRM-funded activity.

SECTION 100310. MARCH-IN RIGHTS

Purpose:

This section describes the circumstances under which the CIRM may exercise its right to require a grantee to grant an exclusive or non-exclusive license or exercise those rights itself.

Subdivision (a) states with regard to CIRM-funded patented inventions that the CIRM shall have the right to require the grantee, or exclusive licensee of a CIRM-funded invention, to grant a licensee in any field of use to a responsible applicant upon reasonable terms, and reserves the right of the CIRM itself to grant such a license if the grantee or licensee so refuses. The subdivision describes the circumstances under which the CIRM will act: 1) if the grantee or licensee has not made responsible efforts in a reasonable time to achieve practical application of a CIRM-funded patented invention; 2) if the licensee has failed to adhere to the given plan for access to resultant therapies; 3) failure by the licensee/grantee to adhere to requirements for public use; or 4) to alleviate a public health or safety emergency.

Subdivision (b) describes the process by which the grantee or licensee will be notified by the CIRM of its intent to exercise the rights described in this regulation and the timeline for allowing the licensee or grantee to cure the deficiency. This subdivision specifies that action taken by the CIRM to address a public health or safety emergency may be taken at any time.

Rationale:

CIRM maintains a mandatory licensing provision commonly referred to as the march-in authority, the purpose of which is to prevent the underutilization of CIRM-funded inventions. March-in would apply only to those research tools that could be defined as patentable inventions. Prior to exercising march-in rights, CIRM must determine that such action is necessary because of the failure of the grantee organization or its licensees to take effective steps to achieve practical application of the inventions in a particular field of use, to satisfy health or safety needs, or to meet requirements for public use. Unlike the research exemption license retained by CIRM, the march-in provision is not limited to use for research purposes. CIRM march-in rights may be exercised in the event of (but are not limited to) failure to license CIRM-funded patentable inventions, failure to meet plans outlined in license agreements, or failure to provide adequate availability of resultant products for the public use.

In observance of the march-in provision, CIRM grantee organizations may not assign to a third party all rights to an invention, although exclusive licensing is permitted under the CIRM IPPNPO.

CIRM will give to the grantee or licensee notice of such determination and the basis on which it was made. CIRM will not exercise its rights described above if the grantee or licensee takes diligent action promptly to cure the deficiency and such deficiency is cured not more than one year from receipt of notice (or longer period if agreed to by CIRM). With respect to a deficiency described in subdivision (a)(4), the CIRM may exercise such right at any time in the event of a public health or safety emergency. This is an appropriate tool in emergencies and is consistent with federal march-in provisions for federally-funded research.